#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Epstein et al.

Examiner: Richard A. Schnizer

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Title: Aptamers Comprising CpG Motifs (as previously amended)

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Cambridge, Massachusetts

# AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION UNDER 37 C.F.R. § 1.116

This is an Amendment and Response to the Final Office Action having a mailing date of November 5, 2009, which has a shortened statutory period set to expire February 5, 2010, and an extended period set to expire March 5, 2010. Applicants hereby petition the Office for a onemonth extension of time for responding to the Action.

Applicants request entry of this Amendment and Response because applicants have cancelled a part of an independent claim and have presented rejected claims in better form for consideration on appeal.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

## Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in this application:

Claims 1-10 (cancelled).

Claim 11 (currently amended). An aptamer comprising a first nucleic acid sequence that binds to a first target and a second nucleic acid sequence that binds to a second target, wherein the second sequence is an immunostimulatory CpG motif that stimulates an immune response, wherein the CpG motif comprises the formula rCGyy, wherein "r" is a purine, "C" is cytosine, "G" is guanosine and "y" is a pyrimidine, and wherein the first sequence binds to a first target selected from the group consisting of PDGF, IgE, IgE Fcs R1, prostate-specific membrane antigen (PSMA), CD22, TNF-alpha, CTLA4, PD-1, PD-L1, PD-L2, FcRIIB, BTLA, transmembrane protein containing immunoglobulin and mucin-like domains (TIM-3), CD11c, B lymphocyte activating factor (BAFF), B7-X, CD19, CD20, CD25 and CD33.

Claims 12-13 (cancelled).

Claim 14 (previously presented). A pharmaceutical composition comprising the aptamer of claim 11, a cytotoxic agent and a pharmaceutically acceptable carrier.

Claim 15 (previously presented). The composition of claim 14, wherein the cytotoxic agent belongs to a class of cytotoxic agents selected from the group consisting of tubulin

stabilizers, tubulin destabilizers, anti-metabolites, purine synthesis inhibitors, nucleoside analogs, DNA alkylating agents, DNA modifying agents and vascular disrupting agents.

Claim 16 (previously presented). The composition of claim 14, wherein the cytotoxic agent is selected from the group consisting of calicheamycin, doxorubicin, taxol, methotrexate, gemcitabine, cytarabine, vinblastin, daunorubicin, docetaxel, irinotecan, epothilone B, epothilone D, cisplatin, carboplatin and 5-fluoro-U.

Claims 17-64 (cancelled).

#### REMARKS

Claims 11 and 14-16 are pending. Claims 1-10, 12-13 and 17-64 were previously cancelled. Claim 11 has been amended to delete reference to one of the targets in the Markush group. Accordingly, no new matter has been added.

## Rejection under 35 U.S.C. § 102

Claims 11 and 14-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lupold *et al.* ("U.S. Patent Application Publication No. 2002/0119473).

For the reasons stated previously in applicants' Amendment and Response dated September 9, 2009, applicants respectfully disagree.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. M.P.E.P. § 2131. The elements must also be arranged as required by the claim. M.P.E.P. § 2131. Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. M.P.E.P. § 2131.

Independent claim 11, as amended, and the claims that depend therefrom, are directed to an aptamer comprising a first nucleic acid sequence that binds to a first target and a second nucleic acid sequence that binds to a second target, wherein the second sequence is an immunostimulatory CpG motif that stimulates an immune response, wherein the CpG motif comprises the formula rCGyy, wherein "r" is a purine, "C" is cytosine, "G" is guanosine and "y" is a pyrimidine, and wherein the first sequence binds to a first target selected from the group consisting of PDGF, IgE, IgE Fcɛ R1, CD22, TNF-alpha, CTLA4, PD-1, PD-L1, PD-L2, FcRIIB, BTLA, transmembrane protein containing immunoglobulin and mucin-like domains (TIM-3), CD11c, B lymphocyte activating factor (BAFF), B7-X, CD19, CD20, CD25 and CD33.

Lupold *et al.* ("Lupold") disclose aptamers to PSMA and methods for generating aptamers to PSMA. Lupold discloses a number of PSMA aptamers, including xPSM-A9 and

xPSM-A10. Lupold also discloses that the PSMA aptamers are useful for the delivery of

therapeutic compounds to tissues or organs expressing PSMA.

Even though applicants disagree with the examiner that Lupold inherently anticipates the

claimed invention, in order to expedite prosecution, applicants have amended independent claim

11 to delete reference to PSMA as a first target. Lupold does not show an aptamer directed to a

target other than PSMA. Accordingly, withdrawal of this rejection under 35 U.S.C. § 102(b) is

respectfully requested.

**CONCLUSION** 

Applicants submit that claims 11 and 14-16 are now in allowable form. Accordingly,

reconsideration of the rejection and allowance of the claims at an early date are earnestly

solicited.

If there are any questions regarding this Amendment and Response or if the undersigned

can be of assistance in advancing the application to allowance, please contact the undersigned at

the number set forth below.

Respectfully submitted,

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